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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,048	12/15/2003	David E. Lowery	PHRM0002-104(6297.1.DV1)	5604

34135 7590 10/06/2006

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,048

Applicant(s)

LOWERY ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-82 is/are pending in the application.
- 4a) Of the above claim(s) 65-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63,64,69-71,73-78, 80-82 is/are rejected.
- 7) ☒ Claim(s) 72 and 79 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/15/03, 8/20/04, 4/26/04, 9/12/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group V, claims 63 and 64 (both in part), 69, 70-76 (all in part), in the reply filed on 07/13/2006 is acknowledged. The traversal is on the ground(s) that the five patentable distinct species are joined by the generic claim 63 and an allowable generic claim may link a reasonable number of species embraced by it. The Examiner notes the following: Claim 63 links inventions groups I-V. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim, claim 1. Upon the indication of allowability of the linking claim, the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory

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double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

2. The preliminary amendments filed on 12/15/2003 and 07/13/2006 have been entered in full. Claims 64 and 69 have been amended. New claims 77-82 have been added. Claims 63-82 are pending. Claims 63, 64, and 69-82 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

3. The Information Disclosure Statements submitted on 12/15/2003, 08/20/2004, 04/26/2004, and 09/12/2006 have been received by the Office and the listed references have been considered by the Examiner.

Claim Rejections—35 USC § 112, 1st paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 63, 64, 69-71, 73-78, and 80-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification

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in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 63, 64, 69-71, 73-78, and 80-82 are drawn to a method for identifying a modulator of binding between a DmGPCR and an allatostatin, wherein the DmGPCR having a sequence with at least 90% sequence homology to SEQ ID NO: 8. The claims do not require that the DmGPCR4 possess any particular biological activity, nor any particular conserved structure, nor other disclosed distinguishing feature. Thus, the claims are drawn to a method of identifying a modulator of binding between DmGPCR4 of SEQ ID NO: 8 or a variant thereof and an allatostatin.

The instant disclosure of DmGPCR4 of SEQ ID NO: 8 and its encoding nucleic acid do not provide adequate written description for the genus of DmGPCR4 of SEQ ID NO: 8 and its variants encompassed in the claims. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a

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substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant disclosure fails to provide sufficient description information, such as definitive structural or functional features of the genus of DmGPCR4 receptors. There is no description of the conserved regions that are critical to the structure and function of the genus of DmGPCR4 receptors. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed DmGPCR4 receptors.

Accordingly, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DmGPCR4 receptors and thus the claimed methods.

Claim Rejections—35 USC §112, 2nd paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 75, 76, and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 75, 76, and 82 are indefinite because they recite "one or more properties of the binding modulator". It is not clear what properties of the binding

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modulator are referred to. Neither the specification nor the art define the term unambiguously, rendering the claims indefinite.

Claim Objections—Minor Informalities

8. Claim 63, 64, and 69-82 are objected to because of the following informalities: (i). claims 63, 64, and 70-82 recite non-elected subject matter (non-elected SEQ ID NO for allatostatin): (ii). The word "allatostatin" in claims 63, 64, and 69 is spelled as "allostatin" (see, e.g., pages 100-101 of the specification). Appropriate correction is required.

9. The prior art made of record (Form PTO-1449) and not relied upon is considered pertinent to Applicant's disclosure.

Lenz et al. (*Biochem. Biophys. Res. Commun.* 273:571-577, 2000) teach cloning a Drosophila receptor, which is 100% identical to the DmGPCR4 of SEQ ID NO: 8 of the present invention. Lenz et al. also teach that the Drosophila receptor is a probable allatostatin receptor, based sequence homology. However, Lenz et al. do not teach or suggest the instantly claimed invention in its entirety.

Conclusions

10. No claims are allowable.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
October 1, 2006

RUIXIANG LI, PH.D.
PRIMARY EXAMINER